510(k) Summary

k130236

1 Administrative

MAR 1 5 2013

Device Information	
Device Name:	Range+ QUALICHECK, LEVEL 1 Range+ QUALICHECK, LEVEL 2 Range+ QUALICHECK, LEVEL 3
Common Name:	Quality Control
Product Code:	JJS
Registration Number:	21 CFR 862.1660
Classification:	Class I, Reserved
Classification Panel:	Clinical Chemistry

Submitter	
Company Name:	Radiometer Medical ApS
ER Number:	3002807968
Address:	Aakandevej 21 2700 Broenshoej Denmark
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2 Description of Device

Range+ QUALICHECK is a three level quality control system consisting of:

- Range+ QUALICHECK, LEVEL 1 (S7930)
- Range+ QUALICHECK, LEVEL 2 (S7940)
- Range+ QUALICHECK, LEVEL 3 (S7950)

Each level consists of 30 ampoules per box. One ampoule contains 2 mL of solution.

The quality control solution is an aqueous solution containing a biological buffer, salts, glucose, lactate, dyes and a preservative, and it is equilibrated with carbon dioxide and oxygen.

3 Intended Use

For In Vitro Diagnostic Use. This Range+ QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are:

pH, *p*CO2, *p*O2, *c*tHb, *s*O2, *F*O2Hb, *F*COHb, *F*MetHb, *F*HbF , *c*K+, *c*Na+, *c*Ca2+, *c*Cl–, *c*Glu, *c*Lac, ctBil

4 Substantial Equivalence

The Range+ QUALICHECK Level 1-3 is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacture:
k980135 QUALICHECK5+, Radiometer Medical ApS

Similarities		
Issue	**SE Device**	**Predicate: QUALICHECK5+ (K980135)**
Form	Same	Liquid
Base matrix	Same	Aqueous solution
Preservatives	Same	ProClin 950
Open Vial Claim	Same	Ampoules should be conditioned for at least five hours at a constant temperature between 18 °C and 32 ° before use. To maintain the reliability of the blood gas parameters, you must use the contents of the ampoule immediately after opening and according to the instructions in the operator's manual for the relevant analyser.
Blood Gas Measurement	Same	pH, pO_2, pCO_2
Oximetry Measurement	Same	*c*tHb, sO_2 FO_2Hb, *F*COHb, *F*MetHb
Electrolyte Measurement	Same	cK^+, cNa^+, cCa^{2+}, cCl^-
Metabolite Measurement	Same	*c*Glucose, *c*Lactate
Hemoglobin Measurement	Same	ctBil
Compatible analyzers	Same	• ABL700/705/710/715/720/725/730/735 • ABL805/810/815/820/825/830/ 835 • ABL80 - OSM SW • ABL90 FLEX

Differences		
Issue	**SE Device**	**Predicate: QUALICHECK5+ (K980135)**
Intended Use	For In Vitro Diagnostic Use. This Range+ QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges. Analytes are: pH, pCO_2, pO_2, *c*tHb, *s*O2, FO_2Hb, *F*COHb, *F*MetHb, *F*HbF , cK^+, cNa^+, cCa^{2+}, cCl^-, *c*Glu,	For In Vitro Diagnostic Use. This QUALICHECK5+ solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges. For professional use.
Storage	2 °C to 8 °C until expiration date 5 hours between 18 – 32°C	2 °C to 25 °C until expiration date, including up to a total of 15 days at up to 32 °C
Oximetry Measurement	*F*Hbf in Level 1	*F*Hbf in all four levels
Levels	Three levels	Four levels
Target ranges	Target ranges, see Section 12.02 Target values	Target ranges, see Section 12.02 Target values

5 Stability

Stability studies and claims are based on real-time study. Control solutions are stable for 2 years at 2-8°C.

In-use Stability: Ampoules should be conditioned for at least 5 hours at a constant temperature between 18-32°C before use. The contents should be used immediately after opening.

6 Value Assignment

To determine the assigned values and control ranges for Range+ QUALICHECK, six (6) trays of 1000 ampoules are sampled randomly from the Range+ QUALICHECK batch. Twelve ampoules are sampled from each of the trays and 72 ampoules are sampled from the reference batch. The samples are conditioned and shaken at 25°C in a water bath for 6 hours. Measurements are performed on a minimum of 3 validated ABL7xx series devices with data collection. Measurement of each parameter is performed alternately on the reference ampoule and the sample ampoule and repeated 12 times on each ABL7xx for a total of 144 measurements. Target ranges are calculated based on the mean ±2SD.

7 Conclusion

The Range+ QUALICHECK Level 1, Level 2 and Level 3 are substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate device: QUALICHECK5+(K980135).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Radiometer Medical Aps
c/o Martin Gabler
Regulatory Affairs
Akandevej 21
2700 Bronshoj, Denmark

Re: k130236
Trade/Device Name: Range+ QUALICHECK, LEVEL 1
Range+ QUALICHECK, LEVEL 2
Range+ QUALICHECK, LEVEL 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJS
Dated: January 24, 2013
Received: February 8, 2013

Dear Mr. Gabler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130236

Device Name: Range+ QUALICHECK, LEVEL 1
Range+ QUALICHECK, LEVEL 2
Range+ QUALICHECK, LEVEL 3

Indications for Use:

For In Vitro Diagnostic Use. This Range+ QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are:
pH, pCO_2, pO_2, ctHb, sO_2, FO_2Hb, FCOHb, FMetHb, $FHbF^{\cdot}$, cK^+, cNa^+, cCa^{2+}, cCl^-, cGlu, cLac, ctBil

Prescription Use __X____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130236